

Exhibit J

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FILED UNDER SEAL

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY,)
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 Plaintiff,)
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 vs.) No. 07-8379 (RJS)
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 ULTREO, INC.,)
)
)
 Defendant.)
)
)

DEPOSITION OF JAMES C. MCINNES

December 4, 2007

Seattle, Washington

PORTIONS DESIGNATED ATTORNEYS' EYES ONLY

1 four aims of that phase two application are?

2 A It is, with the exception of the dollar figures at
3 the end.

4 I don't think those are in the original aims.

5 Q So that's a summary to let the board of directors
6 know how much money is allocated to each aim; is that
7 correct?

8 A Actually, I don't think the-- it was isolated within
9 the grant, but I probably approximated it here.

10 Q If you look at the bottom of this page, it has a
11 schedule listed.

12 Do you see that?

13 A I do.

14 Q And aim four is human clinical studies, and it lists
15 three studies underneath that.

16 Study one is cleans faster, study two is cleans
17 deeper, and study three is the long-term safety and
18 efficacy.

19 Is that correct?

20 A That's correct.

21 Q Are those the three studies you proposed to the NIH
22 in your application?

23 A I believe it is.

24 Q In the cleans faster study, has Ultreo done the
25 cleans faster study?

1 A We have done an iteration of the cleans faster study.

2 It isn't directly as laid out in the SBIR
3 application but is substantially similar.

4 Q Which study is that we talked about?

5 A The Biosci plaque removal, one minute versus two
6 minutes.

7 Q And that was one minute Ultreo, two minutes Ultreo,
8 and Sonicare, correct?

9 A Sonicare with two minutes, yes.

10 Q And that's already been completed?

11 A That has.

12 Q And the study two is the cleans deeper study,
13 correct?

14 A Yes.

15 Q And what is that study?

16 A In the grant application, I believe it was outlined
17 as being a comparative to another power brush in
18 terms of cleaning in the interproximal location via a
19 floss sampling technique.

20 Q If I remember correctly, it described it would
21 include 55 subjects in the SBIR application. Is that
22 consistent with your memory?

23 A I would have to see the documents to remember the
24 exact number of subjects.

25 Q And have you done this study?

1 A No, we have not.

2 Q Are you intending to do this study?

3 A We currently have no plans to do the study.

4 Q Has a decision been made that you will not do the
5 study?

6 A Not formally.

7 We went through the processes with the University
8 of Washington to essentially set up the study to be
9 done, and then we had doubts about its methodology
10 and the costs associated with doing it in relation to
11 the other two studies, and so we have not formally
12 said we're not going to, but we don't really have
13 plans to go forward with it.

14 Q So you have-- you said you've gone through, with the
15 University of Washington, to set up the study.

16 What does that mean?

17 A To sponsor the study at various institutions, and
18 I'll use the University of Washington as an example
19 of what we did, we will identify someone we're going
20 to work with at the site, we develop a protocol
21 together, that protocol is then submitted to an IRB
22 for approval.

23 There was also a contract that's put in place and
24 agreed upon by the university and Ultreo.

25 You identify resources and timing of when it

1 A We did.

2 Q And that's on file at the university?

3 A Well, I believe it is.

4 I'm not sure the contract was finalized.

5 We probably got it to a point where we agreed
6 upon the terms, but I don't think that it was
7 necessarily signed to execute--

8 Q When did you reach the point to agree upon the terms?

9 A I don't recall specifically.

10 Q Generally?

11 A It would probably be in 2006 would be my guess.

12 We had to have-- in order to receive the grant,
13 we had to have IRB approval, so--

14 Q To receive the grant from the NIH, you had to have
15 IRB approval?

16 A Yes.

17 Q So once you got IRB approval, did you submit that to
18 the NIH?

19 A Yes.

20 Q As part of the documentation to receive the funds?

21 A Yes.

22 Q And then once you got the IRB approval in place, what
23 next did you do in connection with this study?

24 A We then looked at how much we essentially could
25 afford to do on the funding from the grant.

1 These studies turned out to be more expensive
2 than we anticipated, so we weren't able to afford to
3 do all three.

4 We looked at what is a priority in terms of
5 what's important. We felt the long-term gingival
6 health to be most important, so that became our
7 priority.

8 We had questions about the methodology of the
9 cleans deeper. It used an interproximal sampling of
10 a floss technique, and the university had no current
11 skills in doing that. They would have had to have
12 developed and validated the methodology, and we felt
13 that because of these methodology issues and
14 financial issues, that this would be our lowest
15 priority.

16 Q When was that decision made?

17 A I don't recall a specific date of the decision. I
18 think it just became evident throughout 2006,
19 probably in the latter half of 2006, that we wanted
20 to proceed with the long-term study and the cleans
21 faster study first.

22 Q So you wanted to proceed with them first?

23 A Yes.

24 Q So do you intend to still proceed with the cleans
25 deeper study?

1 A As I said previously, we're still conducting research
2 in this grant period, and so we could.

3 We don't have the current intent to, but if we
4 felt there was a reason to, we could revive it and
5 execute it.

6 Q So you have no current plans to conduct the cleans
7 deeper study?

8 A Correct.

9 Q Did you notify the NIH of your decision-- of your
10 intention to not conduct the cleans deeper study?

11 A As of our last reporting of the grant, which was
12 probably reported this year, we talked about the
13 clinical study, primarily the gingivitis study that
14 we're doing. We did not mention that we're not doing
15 the study, but as I mentioned, we haven't formally
16 said we're not going to do it. We've just, at this
17 point, put it on third priority.

18 Q And are you intending to notify the NIH that you're
19 not planning to do the study?

20 A Once we have formally decided that we won't, then I
21 think it would be appropriate that we would contact
22 the NIH and disclose that.

23 Q How long is the study to take?

24 A I believe it's a one-month-- I would have to look at
25 the protocol, but it would be about a one-month

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DEPOSITION OF JAMES C. McINNES, VOLUME 2

December 5, 2007

Seattle, Washington

1 challenged?

2 A Potentially that's correct.

3 Q And you thought that any claims involving the
4 synergistic effect were likely to be challenged?

5 A Potentially.

6 Q Were there any other claims that you thought were
7 likely to be challenged?

8 A Not that I recall. But again, putting together a
9 claims substantiation, you know, you look at all of
10 your products and -- or all of your claims. If you
11 have preference claims, you know, we anticipate some
12 of that may be challenged.

13 So I mean if you're making a claim, I think it's
14 appropriate to support your claims such that if
15 anybody challenges it that you have the required
16 documentation for the claim.

17 Q As you were preparing your claim substantiation
18 documents, you did that because you anticipated
19 potential litigation?

20 A We anticipated that we needed to support the claims in
21 various categories, such as retail, as we discussed
22 yesterday. But we also anticipated that those may
23 become important documents for litigation and to
24 provide the support for the claims that we are making.

25 Q So as you drafted those documents, you were